UNITED STATES DISTRICT COURT FOR THE
DISTRICT OF NEW HAMPSHIRE

Marine Polymer Technologies, Inc.

v. Civil No. 06-cv-100-JD
Opinion No. 2008 DNH 095

HemCon, Inc.

O R D E R

Marine Polymer Technologies, Inc. brings patent infringement claims against HemCon, Inc., alleging infringement of United States Patent No. 6,864,245 ("'245 patent"). HemCon alleges counterclaims that the '245 patent is unenforceable and invalid and seeks a declaration that it is not infringing the '245 patent. The parties dispute the meaning of the terms "biocompatible poly-ß-1→4-N-acetylglucosamine and biocompatible poly-ß-1→4-glucosamine" as used in the '245 patent claims. The parties filed briefs in support of their claim construction, and a Markman hearing was held on March 27, 2008.

Background

The '245 patent is titled "Biocompatible Poly-ß-1→4-N-acetylglucosamine." It is the most recent patent obtained in a family of fifteen related patents that share substantially the same specification. The original application, No. 08/160,569,

was filed on December 1, 1993. The examiner concluded that the application covered multiple inventions and issued a restriction requirement. In response, Marine Polymer pursued different inventions in separate applications.

Poly-ß-1→4-N-acetylglucosamine, abbreviated to p-GlcNAc, is used in a variety of medical products, including wound dressings and bandages. P-GlcNAc occurs naturally in crustacean shells, fungal cell walls, and microalgae such as diatoms. Naturally occurring p-GlcNAc is called chitin, which includes contaminants in varying degrees. When the acetyl group is chemically removed from chitin, it becomes chitosan. The beneficial properties of chitin or p-GlcNAc have been known for nearly two hundred years. The problem encountered in using chitin in medical applications was the variable quality of the product. The inventions in the family of patents including the '245 patent all relate to various inventions involving p-GlcNAc.

Discussion

The disputed terms in this case are biocompatible poly-ß-1→4-N-acetylglucosamine and biocompatible poly-ß-1→4-glucosamine. Marine Polymer construes the terms to mean:

> biomedically pure poly-ß-1→4-N-acetylglucosamine that reproducibly exhibits acceptably low levels of adverse bioreactivity, as determined by biocompatibility tests

> [and] biomedically pure poly-ß-1→4-N-glucosamine that reproducibly exhibits acceptably low levels of adverse bioreactivity, as determined by biocompatibility tests.

Pl. Br. (doc. no. 48-2) at 7. HemCon interprets biocompatible poly-ß-1→4-N-acetylglucosamine to mean:

> the species of material harvested from plant microalgae (microalgae, e.g., diatoms, are living aquatic organisms that capture light energy through photosynthesis, using it to convert inorganic substances into organic matter), and more particularly a species of microalgae that is free of protein, substantially free of other organic contaminants, substantially free of inorganic contaminants, has about 4,000 to about 150,000 N-acetylglucosamine monosaccharides covalently attached in a ß-1→4 conformation, and a minimum molecular weight of about 800,000 daltons.

Def. Br. (doc. no. 47) at 2-3. HemCon interprets biocompatible poly-ß-1→4-N-glucosamine to mean:

> the species of material harvested from plant microalgae, and more particularly the species of microalgae that is free of protein, substantially free of other organic contaminants, substantially free of inorganic contaminants, has about 4,000 to about 150,000 N-acetylglucosamine monosaccharides covalently attached in a ß-1→4 conformation, and a minimum molecular weight of about 640,000 daltons.

Id. In summary, Marine Polymer's construction of the disputed terms focuses on the meaning of "biocompatible" while HemCon's construction focuses on the source of the material used to make the product.

On the day before the Markman hearing, HemCon filed two supplemental glossaries and a glossary of scientific terms,

addressing additional terms not previously identified as disputed. The glossaries repeat HemCon's source limitation in the definition of p-GlcNAc, but also include new definitions that were not addressed in HemCon's brief. The glossaries define claim terms "biocompatible" as "suited for biomedical applications," "up to 150,000 N-acetylglucosamine monosaccharides covalently attached in a ß-1→4 conformation" as "an identifiable inherent chemical structure comprising monosaccharide sugars attached in a covalent ß (beta)-1→4 molecular conformation, which is shown in Figure 1," and "having a molecular weight of up to about 30 million daltons" as "a high molecular weight." The glossaries also provide definitions of terms not used in the claims.

HemCon's failure to provide any developed argumentation in support of its new definitions hampers the court's ability to consider them. Nevertheless, the new definitions of claim terms are considered in the claim construction analysis. HemCon's proposed definitions of terms not used in the claims are not considered.

A. Claim Construction

Claim construction is a legal determination. Chamberlain Group, Inc. v. Lear Corp., 516 F.3d 1331, 1335 (Fed. Cir. 2008). The words used in a claim are given the "meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed. Cir. 2005). That determination is most reliably based on intrinsic evidence, which is comprised of the claims themselves, the written description as presented in the patent specification, and the prosecution history of the patent. Id. at 1314 & 1316-17. Extrinsic evidence such as dictionaries, treatises, and expert testimony is less reliable. Id. at 1317-18. "Although it is unacceptable to import limitations into a claim from the written description, the specification is always highly relevant to the claim construction analysis." Chamberlain Group, 516 F.3d at 1335.

1. Claims

The '245 patent claims address biocompatible poly-ß-1→4-N-acetylglucosamine and biocompatible poly-ß-1→4-glucosamine with certain differing properties, such as the number of monosaccharides, varying maximum molecular weights, deacetylazation, and test results. For example, in Claim 1 what is claimed is: "A biocompatible poly-ß-1→4-N-acetylglucosamine comprising up to about 150,000 N-acetylglucosamine monosaccharides covalently attached in a conformation and having a molecular weight of up to about 30 million daltons." Col. 71, ll. 57-60. Claim 17 states: "A biocompatible poly-ß-1→4-glucosamine comprising up to about 150,000 glucosamine monosaccharides covalently attached in a ß-1→4 conformation, wherein at least one glucosamine monosaccharide has been acetylated." Col. 72, ll. 50-53.

The claims in the '245 patent do not define "biocompatible" or the chemical compound of which their polymers are formed. The claims do not state or even mention a source material for biocompatible poly-ß-1→4-N-acetylglucosamine and biocompatible poly-ß-1→4-glucosamine. The claims also do not state a minimum molecular weight. Therefore, the claims standing alone do not incorporate the limitations HemCon proposes nor define the terms as proposed by Marine Polymer.

2. Specification

Claim terms are to be construed in the context of the specification, but, at the same time, limitations from the specification cannot be imposed on the claims "absent a clear disclaimer of claim scope." Andersen Corp. v. Fiber Composites, LLC, 474 F.3d 1361, 1373 (Fed. Cir. 2007). In particular, "the importation of claim limitations from a few specification statements or figures into the claims" is not appropriate claim construction. Computer Docking Station Corp. v. Dell, Inc., 519 F.3d 1366, 1374 (Fed. Cir. 2008). Claims should not be construed as limited to specific embodiments described in the specification. Id.

On the other hand, the specification can act as a dictionary for terms used in the claims. Phillips, 415 F.3d at 1323. "When a patent thus describes the features of the 'present invention' as a whole, this description limits the scope of the invention." Verizon Servs. Corp. v. Vonage Holdings Corp., 503 F.3d 1295, 1308 (Fed. Cir. 2007). Similarly, if the specification describes a "critical element," "essential features," "the very character of the invention," or otherwise uses language of requirement rather than preference in describing the invention, the specification may provide a limiting definition that restricts the scope of the claims. Andersen, 474 F.3d at 1366-68; see also

Computer Docking Station, 519 F.3d at 1374 ("For example, repeated and definitive remarks in the written description could restrict a claim limitation to a particular structure.").

Because the fifteen patents that evolved from the original patent application share a common specification, the '245 patent specification is long, complex, and somewhat confusing. When a common specification "repeatedly and consistently describes" the claimed inventions with a particular limitation or describes the "overall inventions" of all of the patents sharing the specification so that the "inescapable conclusion" is that the patents share the same limitation, that limitation is added to claims that are not otherwise explicitly limited. Microsoft Corp. v. Multi-Tech Sys., Inc., 357 F.3d 1340, 1347-48 (Fed. Cir. 2004).

The '245 patent specification defines the invention as relating

> to a purified, easily produced poly-ß-1→4-N-acetylglucosamine (p-GlcNAc) polysaccharide species. The p-GlcNAc of the invention is a polymer of high molecular weight whose constituent monosaccharide sugars are attached in a ß-1→4 conformation, and which is free of proteins, and substantially free of single amino acids, and other organic and inorganic contaminants.

'245 Pat. Abstract; accord Col. 2, ll. 65-67 - Col. 3, ll. 1-14. The inventions described also include "methods for the

purification of the p-GlcNAc of the invention from microalgae, preferably diatom, starting sources . . . [and] methods for derivatization and reformulation of the p-GlcNAc . . . [and] uses of pure p-GlcNAc, its derivatives, and/or reformulations." Id. The summary of the invention section repeats the same description of the '245 patent invention:

> The present invention relates, first, to an isolated, easily produced, pure p-GlcNAc species. The p-GlcNac of the invention is a polymer of high molecular weight whose constituent monosaccharides are attached in a ß-1→4 conformation, and which is free of proteins, substantially free of other organic contaminants, and substantially free of inorganic contaminants.

Col. 4, ll. 9-15. A similar description appears in Section 5.1.

a. HemCon's Construction

HemCon primarily argues that the specification limits the invention to p-GlcNAc produced from microalgae. As introduced in its new glossaries, HemCon also contends that the specification supports a particular definition of "biocompatible," "up to 150,000 N-acetylglucosamine monosaccharides covalently attached in a ß-1→4 conformation," and "having a molecular weight of up to about 30 million daltons." Marine Polymer disputes the microalgal limitation but had little opportunity to address the new glossaries.

I. p-GlcNAc Source Limitation

HemCon relies on the following parts of the specification to support its contention that p-GlcNAc is limited to microalgae sources. The summary of the invention section of the specification states: "The material produced in the present invention is highly crystalline and is produced from carefully controlled, aseptic cultures of one of a number of marine microalgae, preferably diatoms, which have been grown in a defined medium." Col. 4, ll. 22-24. Section 5.2.1, addressing "Methods of Producing Microalgal Sources of p-GlcNAc," states: "The p-GlcNAc of the invention is produced by, and may be purified from, microalgae, preferably diatoms. The diatoms of several genuses and numerous species within such genuses may be utilized as p-GlcNAc starting sources. Each of these diatoms produce p-GlcNAc." Col. 10, ll. 66-67; Col. 11, ll. 1-6. HemCon also contends that the specification repeatedly requires microalgae, specifically diatoms, as the source for biocompatible poly-ß-1→4-N-acetylglucosamine and biocompatible poly-ß-1→4-glucosamine and quotes sections of the specification that describe the preferred embodiment, methods of purification, and specific microalgal sources for p-GlcNAc.

Marine Polymer responds that the '245 patent claims are composition claims that do not claim a process or method of

making the composition or a source of the claimed composition. Marine Polymer contends, "the present invention" described in the summary section is a different invention within the fifteen-patent family covered by the same specification, claiming a method for producing p-GlcNAc. Marine Polymer points out that Section 5.2.1, which HemCon relies on, addresses "Methods of Producing Microalgal Sources of p-GlcNAc."

In contrast, the section of the specification devoted to "p-GlcNac," which is Section 5.1, provides the following descriptions:

> The p-GlcNAc polysaccharide species of the invention is a polymer of high molecular weight ranging from a weight average of about 800,000 daltons to about 30 million daltons, based upon gel permeation chromatography measurements. Such a molecular weight range represents a p-GlcNAc species having about 4,000 to about 15,000 N-acetylglucosamine monosaccharides being preferred.
>
> The variability of the p-GlcNAc of the invention is very low, and its purity is very high, both of which are evidenced by chemical and physical criteria.
>
> Further, the p-GlcNAc of the invention exhibits a very low percentage of bound water.
>
> The pure p-GlcNAc of the invention exhibits a carbohydrate analysis profile substantially similar to that shown in FIG. 2. The primary monosaccharide of the pure p-GlcNAc of the invention is N-acetylglucosamine. Further, the pure p-GlcNAc of the

> invention does not contain the monosaccharide glucosamine. [T]he p-GlcNAc of the invention is of high purity and crystallinity.
>
> NMR analysis of the pure p-GlcNAc of the invention . . . indicates not only data which is consistent with the p-GlcNAc of the invention being a fully acetylated polymer, but also demonstrates the lack of contaminating organic matter within the p-GlcNAc species.
>
> The p-GlcNAc of the invention exhibits a high degree of biocompatibility. Biocompatibility may be determined by a variety of techniques, including, but not limited to such procedures as the elution test, intramuscular implantation, or intracutaneous or systemic injection into animal subjects. . . . The Working Example presented in Section 10, below, demonstrates the high biocompatibility of the p-GlcNAc of the invention.

Col. 9-10. Section 5.1 does not mention microalgae, diatoms, or any other source of the p-GlcNAc of the invention. In addition, Section 5, "Detailed Description of the Invention," explains that it first presents "a description of physical characteristics of the purified p-GlcNAc species of the invention" and then "methods are described for the purification of the p-GlcNAc species of the invention from microalgae, preferably diatom, starting sources." Col. 8, ll. 66-67, Col. 9, ll. 1-4. Section 5.1 describes the p-GlcNAc of the invention. The absence of a reference to microalgae or diatoms there undermines HemCon's theory that the specification imposes a source limitation on the claims in the '245 patent.

HemCon notes that in contrast to microalgal sources, crustacean shells are not mentioned as a means of practicing the invention. As a result, HemCon urges, the '245 patent does not show how crustacean sources could be used to practice the invention and therefore lacks enablement. HemCon also argues that because only one embodiment of the invention, p-GlcNAc made from microalgae, was disclosed in the '245 patent, the claims are limited to that embodiment.

Patent claims, however, may be broader than the embodiments disclosed in the specification. Nazomi Commc'ns, Inc. v. ARM Holdings, PLC, 403 F.3d 1364, 1369 (Fed. Cir. 2005). In addition, a patent that discloses only one embodiment does not necessarily limit its claims to that embodiment. Phillips, 415 F.3d at 1323; accord Saunders Group, Inc. v. Comfortrac, Inc., 492 F.3d 1326, 1332 (Fed. Cir. 2007). Unless the specification clearly limits the invention to the disclosed embodiments or to a particular structure, every embodiment of an invention need not be disclosed. Liebel-Flarsheim Co. v. Medrad, Inc., 348 F.3d 898, 906-09 (Fed. Cir. 2004). In addition, whether claims in the '245 patent are invalid due to a lack of enablement is not an appropriate basis on which to import limitations from the specification. See Nazomi Commc'ns, 403 F.3d at 1368 (holding that although claims should be construed to preserve their

validity if possible, courts cannot rewrite claims for that purpose); Rhine v. Casio, Inc., 183 F.3d 1342, 1345 (Fed. Cir. 1999) (same).

HemCon further argues that its claim construction, limiting biocompatible poly-ß-1→4-N-acetylglucosamine and biocompatible poly-ß-1→4-glucosamine to material made from microalgae, is supported by the specification's rejection of crustacean sources. In the background section, the specification states that chitin from conventional sources such as crustacean outer shells was "unpredictably variable," which precluded its use for medical applications. Col. 3, ll. 40-41. The specification, however, also rejected chitin from microalgae because it contained proteins and other contaminants.[1] Col. 3, ll. 50-55. Therefore, in this case, the background section states the problem with the previously-existing chitin from both crustacean and microalgae sources, which the '245 patent invention solved, but does not limit the source of the product claimed by the '245 patent. See Ventana Med. Sys., Inc. v. Biogenex Labs., Inc., 473 F.3d 1173, 1180 (Fed. Cir. 2006).

The specification, taken as a whole, does not support an "inescapable conclusion" that the biocompatible p-GlcNAc claimed

[1]The reference to "McLachlan" in the background section is to chitin produced from diatoms.

in the '245 patent is limited to a material made from microalgae. Therefore, HemCon's source limitation is not supported by the claims or the specification.

ii. "Biocompatible"

HemCon defines "biocompatible" as used in the '245 patent to mean "suited for biomedical applications." In support of that construction, HemCon cites a section of the summary of the invention that describes uses of p-GlcNAc including "novel commercial applications relating to such industries as the biomedical, pharmaceutical, cosmetic and agricultural industries, all of which require starting materials of the highest degree of purity." Col. 4, ll. 39-43. That discussion continues to the part cited by HemCon: "For example, the p-GlcNAc materials of the invention exhibit properties that make them ideally suited for a large number of biomedical applications. Some of these properties include but are not limited to: high purity and composition consistency; biocompatibility; controllable biodegradability; and, an ability to immobilize and encapsulate agents, such as therapeutic agents, and cells." Col. 4, ll. 48-54.

The cited part of the specification suggests that biocompatibility is only one of many properties of p-GlcNAc that

is suitable for biomedical applications. Section 10 of the specification is titled "p-GlcNAc Biocompatibility." In that section, biocompatibility is defined as exhibiting "no detectable biological reactivity, as assayed by elution tests, intramuscular implantation in rabbits, intracutaneous injection in rabbits, and systemic injections in mice." Col 41, ll. 66-67; Col. 42 ll. 1-3. Therefore, HemCon's definition of biocompatible is not supported by the specification.

iii. "Up to 150,000 N-acetylglucosamine Monosaccharides Covalently Attached in a ß-1→4 Conformation"

HemCon defines the phrase "up to 150,000 N-acetylglucosamine monosaccharides covalently attached in a ß-1→4 conformation," as used in the '245 patent claims to mean "an identifiable inherent chemical structure comprising monosaccharide sugars attached in a covalent ß (beta)-1→4 molecular conformation, which is shown in Figure 1." In support, HemCon cites the summary of the invention description as follows: "The p-GlcNAc of the invention is a polymer of high molecular weight whose constituent monosaccharides are attached in a ß-1→4 conformation, and which is free of proteins, substantially free of other organic contaminants, and substantially free of inorganic contaminants." Col. 4, ll. 11-15.

HemCon's citation to the specification does not support its definition that omits the limit on the number of monosaccharides and adds new language. In addition, the cited reference to the specification does not rely on or even mention Figure 1. HemCon has not shown that the definition it proposes is an appropriate construction.

iv. "Having a Molecular Weight of Up to about 30 million Daltons"

HemCon construes the claim terms addressing molecular weight to mean "a high molecular weight." In support, HemCon cites the specification's description of p-GlcNAc: "The p-GlcNAc polysaccharide species of the invention is a polymer of high molecular weight ranging from a weight average of about 800,000 daltons to about 30 million daltons, based on gel permeation chromatography measurements." Col. 9, ll. 16-19.

The '245 patent claims state an upper limit on molecular weight but do not include a lower limit. Given the stated molecular weights in the claims, a further definition is not necessary. In addition, the absence of a lower weight limit in the claims counsels against importing a limitation through claim construction from the specification.

b. Marine Polymer's Construction

Marine Polymer construes biocompatible p-GlcNAC to mean "biomedically pure poly-ß-1→4-N-acetylglucosamine [and biomedically pure poly-ß-1→4-glucosamine] that reproducibly exhibits acceptably low levels of adverse bioreactivity, as determined by biocompatibility tests." Marine Polymer focuses on the requirement of biocompatibility. HemCon contends that Marine Polymer's claim construction is overly broad, in view of the specification.

Section 5.1, which describes the p-GlcNAc of the invention, provides certain characteristics. The p-GlcNAc of the invention "is a polymer of high molecular weight" with monosaccharides attached in a ß-1→4 conformation. Col. 9, l. 17. "The variability of the p-GlcNAc of the invention is very low, and its purity is very high." Col. 9, ll. 28-30. It "exhibits a very low percentage of bound water" and "does not contain the monosaccharide glucosamine." Col. 9, l. 56; Col. 10, l. 28. "NMR analysis" produces a pattern "which is consistent with the p-GlcNAc of the invention being a fully acetylated polymer" and "demonstrates the lack of contaminating organic matter within the p-GlcNAc species." Col. 10, ll. 37-43. In addition, "the p-GlcNAc of the invention exhibits a high degree of biocompatibility" which "may be determined by a variety of

techniques, including, but not limited to such procedures as the elution test, intramuscular implantation, or intracutaneous or systemic injection into animal subjects." Col. 10, ll. 48-53.

Biocompatibility is addressed as an "Example" presented in Section 10, which is titled "p-GlcNAc Biocompatibility." There the specification states "that the p-GlcNAc of the invention exhibits no detectable biological reactivity, as assayed by elution tests, intramuscular implantation in rabbits, intracutaneous injection in rabbits, and systemic injection in mice." Col. 41, ll. 66-67; Col. 42, ll. 1-3. The remainder of Section 10 describes the materials, methods, and results of the tests done for biocompatibility.

Although Marine Polymer's proposed claim construction generally is supported by the description in Section 5.1, it uses different terminology. Specifically, the terms "biomedically pure" and "reproducibly" do not appear in Section 5.1. A claim construction "that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." Ormco Corp. v. Align Tech., Inc., 498 F.3d 1307, 1313 (Fed. Cir. 2007) (internal quotation marks omitted).

2. Prosecution History

The prosecution history of the '245 patent is also part of claim construction analysis. See Computer Docking, 519 F.3d at 1374. A claim term may be limited in scope during the prosecution of the patent before the PTO if the disclaimer or disavowal of scope is clear and unambiguous. Elbex Video, Ltd. v. Sensormatic Elec. Corp., 508 F.3d 1366, 1371 (Fed. Cir. 2007). A patent's prosecution history includes the original application and the family of related applications and patents. Andersen, 474 F.3d at 1368.

HemCon asserts that in the course of prosecuting related patents, U.S. Patent No. 6,743,783 ("'783 patent) and U.S. Patent No. 6,686,342 ("'342 patent), Marine Polymer disclaimed the use of crustacean sources for poly-ß-1→4-N-acetylglucosamine and poly-ß-1→4-glucosamine. Marine Polymer disagrees and argues that the prosecution history supports its interpretation of the disputed terms.

a. The '783 Patent

The '783 patent issued on June 1, 2004, eight months before the '245 patent. The '783 patent claims "[a] pharmaceutical composition suitable for hemostasis comprising an amount of a microalgal poly-ß-1→4-N-acetylglucosamine, or derivative thereof,

effective for hemostasis, wherein the microalgal poly-ß-1→4-N-acetylglucosamine or derivative thereof is formulated into a shape or configuration suitable for hemostasis." '783 Patent, Col. 70, ll. 10-16.

HemCon contends that Marine Polymer expressly disclaimed the interchangeability of crustacean sources for the poly-ß-1→4-N-acetylglucosamine claimed in the '783 patent and cannot now broaden the scope of the polymer claimed in the '245 patent. Specifically, HemCon points to Marine Polymer's argument in prosecuting the '783 patent that it would not have been obvious to substitute microalgal sources for crustacean sources of hemostasis material, because the prior art pertaining to crustacean sources did not provide motivation to do so.[2] Therefore, Marine Polymer's statement simply answered the examiner's rejection based on obviousness. Because the '783 patent claimed microalgal sources only, that limitation was already in place. Marine Polymer did not clearly and unambiguously disclaim the interchangeability of crustacean and microalgal sources of p-GlcNAc, as HemCon asserts.

[2]Prior art taught the use of crustacean sources of chitin for hemostasis and microalgal sources of chitin for other purposes.

The '783 patent is limited to claims for a composition suitable for hemostasis with microalgal poly-ß-1→4-N-acetylglucosamine. The '783 patent does not claim or address biocompatible poly-ß-1→4-N-acetylglucosamine, which is the subject of the '245 patent. Further, as Marine Polymer points out, the use of the limitation "microalgal" in the '783 patent claims suggests that poly-ß-1→4-N-acetylglucosamine without that limitation was not intended to include a source limitation.

b. The '342 Patent

The '342 patent, which issued on February 3, 2004, and which is part of the same patent family, claims biocompatible poly-ß-1→4-N-acetylglucosamine. HemCon contends that Marine Polymer disclaimed any source other than microalgae based on the examiner's discussion of prior art during the prosecution history of the '342 patent. Specifically, the examiner stated that no prior art taught or suggested N-acetylglucosamine as claimed in the application for the '342 patent. The examiner noted two sources of prior art that taught "an N-acetylglucosamine material made from the same microalgal source as taught by Applicant . . ." but concluded, based on "the Cole declaration," that the prior art was not biocompatible. The examiner also noted other prior art that taught that N-acetylglucosamine could be "formulated" or

shaped into biomedical products but did not teach the same number of monosaccharides or molecular weight or provide the same purity and reproducibility as the p-GlcNAc claimed in the application.

HemCon contends that the examiner limited biocompatible poly-ß-1→4-N-acetylglucosamine in the '342 patent to a microalgal source based on the characterization used and the reference to the number of monosaccharides and molecular weight. HemCon asserts that the number of monosaccharides and molecular weight claimed in the '342 patent preclude crustacean sources. As Marine Polymer points out, however, HemCon failed to produce any evidence to support that theory. The examiner's passing reference to a microalgal source, in the context it was used, is not enough to impose a disclaimer on Marine Polymer.

c. Patent Examiners and Oath

HemCon insinuates that Marine Polymer engaged in misconduct in the course of prosecuting the application for the '245 patent. HemCon asserts that the same examiner reviewed the applications for the '783 and '342 patents and that a different examiner reviewed the application for the '245 patent. HemCon further asserts that Marine Polymer failed to apprise the new examiner of its positions taken during the prosecution of the previous patents, in which, HemCon contends, Marine Polymer had disclaimed

scope that was reclaimed in the '245 patent. HemCon charges that Marine Polymer thereby managed to have the claims in the '245 patent allowed without lower limits on the molecular weight claimed. HemCon also contends that Marine Polymer was required to file a supplemental oath or declaration with the application for the '245 patent to support the new scope of the patent claimed.

HemCon cites no authority to support its theory that a change in examiners imposes duties on the patent applicant which affect claim construction. Similarly, whether a supplemental oath was required has no apparent relevance to claim construction. Therefore, HemCon's novel theories are not considered for this purpose.

B. Conclusion

The terms biocompatible poly-ß-1→4-N-acetylglucosamine and biocompatible poly-ß-1→4-N-glucosamine, as used in the claims of the '245 patent, are construed to mean:

polymers with their stated compositions (poly-ß-1→4-N-acetylglucosamine and poly-ß-1→4-N-glucosamine) and with low

variability, high purity, and no detectable biological reactivity as determined by biocompatibility tests.

SO ORDERED.

Joseph A. DiClerico, Jr.
United States District Judge

May 6, 2008

cc: Daniel R. Johnson, Esquire
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